



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

DEC 26 2001

Dr. Satoshi Takaya, Director  
Division of Export of Meat Products to the United States  
Food Sanitation Department  
Ministry of Health, Labor and Welfare  
1-2-2 Kasumigaseki, Chiyoda-ku  
Tokyo 100-8916, Japan

Dear Dr. Takaya:

The Food Safety and Inspection Service has completed an on-site audit of Japan's meat inspection system. The audit was conducted from August 20 – September 1, 2001.

Enclosed is a copy of the draft final audit report. You are invited to provide comments regarding the information in the audit report. Comments received from the Government of Japan will be included as an attachment to the final report. Comments must be provided within 60 days of the receipt of this letter.

During this audit, our auditor found that two of Japan's three certified establishments had deficiencies in sanitation controls (both pre-operational and operational sanitation), animal disease controls, and slaughter/processing controls. Because of these deficiencies, the establishments were rated as acceptable/re-review. During our next audit, these establishments will be rated either acceptable or unacceptable.

In addition, the following concerns were noted with regard to Japan's meat inspection system.

1. Condemned product was not properly denatured in all three establishments. Condemned products must be denatured or decharacterized with approved denaturants to preclude their use as human food.
2. Suspect animals were not adequately separated from non-suspect animals in all three establishments. Suspect animals must be kept in pens or other facilities that are completely separate from pens holding healthy-appearing animals.
3. Japan is using the sponge method for sampling of product for generic *E. coli* and is using the excision method criteria to evaluate test results. Since Japan is using the sponge method to collect samples (not the excision method), Japan will need to evaluate test results based on Table 1—Evaluation of *E. coli* Test Results (9 CFR 310.25(a)(5)). These are the criteria to use to evaluate test results when an establishment uses the sponge method to take samples for testing. I have enclosed a copy of Table 1 for your information.

Please advise FSIS of the specific actions taken or to be taken by the Government of Japan to correct the deficiencies noted in the draft final audit report and presented above.

If you have any questions regarding the audit or need additional information, please contact me at 202-720-3781. My fax number is 202-690-4040 and my email address is sally.stratmoen@usda.gov.

Sincerely,

/s/ **Nancy Goodwin**

Sally Stratmoen, Chief  
Equivalence  
International Policy Staff  
Office of Policy, Program Development  
and Evaluation

Enclosures

cc:

Suzanne Hale, Minister-Counselor, U.S. Embassy, Tokyo  
Mr. Watanabe, First Secretary, Embassy of Japan, Washington, DC  
Ross Kreamer, FAS Area Officer  
John Prucha, ADA, OPPDE  
Sally Stratmoen, Chief, ES, IPS, OPPDE  
Karen Stuck, Chief, IEPS, IPS, OPPDE  
Donald Smart, Director, Review Staff, OFO  
Nancy Goodwin, ES, IPS, OPPDE  
Amy Winton, State Department  
Country File-Japan (Audit FY 2001—draft final audit to CVO)

FSIS:OPPDE:IPS:NGoodwin:bw:12/20/01:720-9187:Japan-FY2001 audit

<u>Clearance:</u>	<u>Initial</u>	<u>Date</u>
Sally Stratmoen, Chief, ES, FSIS, IPS	_____	_____
Clark Danford, Acting Director	_____	_____